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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,757	02/12/2001	Robert W. Mahley	6510096CIP3	9705

7590

08/08/2002

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/782,757

Applicant(s)

MAHLEY ET AL.

Examiner

Christopher J. Nichols

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6.11.02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4 and 19-22 drawn to a composition comprising an agent that reduces apolipoprotein E4 (apoE4) domain interaction and described pharmaceutical formulations incorporating said agent, classification dependent upon structure of agent.
 - II. Claims 5-7 and 23-27 drawn to a method of reducing apoE4 domain interaction in a cell and bodily fluids including but not limited to serum or interstitial fluids, classification dependent upon structure of agent.
 - III. Claims 8-11, drawn to a method of promoting neuronal cell growth comprising contacting a neuronal cells that produces apoE4 or takes up apoE4 from its environment with an agent that reduces apoE4 domain interaction, whereby neuronal cell growth is promoted, classification dependent upon structure of agent.
 - IV. Claims 12-14, drawn to a method of reducing formation of neurofibrillary tangles in an individual, comprising administering to the individual an effective amount of an agent that reduces apoE4 domain interaction, classification dependent upon structure of agent.
 - V. Claim 15-17, drawn to a method for reducing the risk or the severity of symptom of Alzheimer's disease (AD) comprising administering to an individual at risk or who exhibits symptoms associated with AD and effective amount of an agent that

reduces apoE4 domain interaction, classification dependent upon structure of agent.

VI. Claims 18 and 28, drawn to a method for reducing apoE4-mediated inhibition of neurite outgrowth comprising of contacting a neuron, including but not limited to neurons in an individual, that synthesizes apoE4 or that takes up apoE4 from its environment with an agent that reduces apoE4 domain interaction, classification dependent upon structure of agent.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and each of Inventions II-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of Group I can be used to specifically label or isolate apoE4.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups II-VI are directed to methods that are distinct both physically and functionally, and are not required one for the other.

5. Invention II requires search and consideration of contacting cells alone and in but not limited to serum or interstitial fluid with an organic agent, which is not required by any of the other groups.

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6. Invention III requires search and consideration of promoting neuronal cell growth, which is not required by any of the other groups.
7. Invention IV requires search and consideration of reducing neurofibrillary tangles in but not limited to an individual, which is not required by any of the other groups.
8. Invention V requires search and consideration of methods that reduce the risk that an individual will develop Alzheimer's disease (AD) and reducing the severity of a symptom associated with Alzheimer's disease, which is not required by any of the other groups.
9. Invention VI requires search and consideration of reducing apolipoprotein E4 (apoE4)-mediated inhibition of neurite outgrowth in but not limited to individuals, which is not required by any of the other groups.
10. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.
11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone number for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
August 7, 2002



ELIZABETH KEMMERER
PRIMARY EXAMINER